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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,912	01/12/2001	Willem Frederik Van Eelen	BO42358	4846

7590 09/09/2004

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Arlington, VA 22202

EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/581,912	VAN EELEN ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *8/30/04*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 16-32 are pending and under examination.

Please submit a request for a corrected filing receipt which includes the foreign priority claim.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

INVENTORSHIP

In view of the papers filed 6/21/04, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(b). The inventorship of this application has been changed by deleting all inventors except for W.F. van Eelen.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

Claims 24 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if applicant intends to limit claim 24 to a puree or if it is open to the members of the Markush group in claim 23 because it has not been phrased so as to exclude members of the Markush. Further, in claim 32 there is no precedent for the recitation "soup, stew, sausage" etc. in claim 30.

Claim Rejections - 35 USC § 102

Claims 16-21, 23-29, 31, 32 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yamamoto *et al.* [U] or Molnar *et al.* [V].

The claims are directed to a meat product consisting of *in vitro* produced animal cells in a three dimensional form, free of fat, tendon, bone, gristle, wherein the cells are selected from muscle, stem or somite cells, and wherein the product is suitable for animal or human consumption.

Yamamoto *et al.* disclose smooth muscle cells produced in vitro in a three dimensional form. The product has not been cultured with antibiotics. (See page 13, Materials and Methods) and is, thus, suitable for animal/human consumption.

Molnar *et al.* disclose skeletal muscle cells in a three dimensional form which have not been cultured with antibiotics (page 387, Materials and Methods) and is, thus, suitable for animal/human consumption.

Claim Rejections - 35 USC § 103

Claims 22 and 30 remain/is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto *et al.* [U] or Molnar *et al.* [V].

Claims 22 and 30 are directed to a mass limitation of the cultured muscle cell product.

Neither Yamamoto *et al.* nor Molnar *et al.* disclose any limitations to the potential scale of the process or the amount of product produced. Changes in the size of a product where the product would not perform differently the prior art is not sufficient to overcome the prior art. See MPEP 2144.04 IV. A.

Although the use to which the product may be put in the prior art is not the same use as the instant use, the product AS CLAIMED is not distinct from the product AS DISCLOSED in the prior art. Please note the instant claims are product claims, not method claims.

Response to Arguments

Applicant's arguments filed 6/21/04 have been fully considered but they are not persuasive.

Applicants argue that Yamamoto et al. does not disclose a product suitable for human/animal consumption because the cells are cultured in bovine serum with penicillin, streptomycin and recombinant growth factors.

Please see the reference at page 13, column 1, line 17 where the aorta from which the cells are obtain has been washed in MEM with penicillin/streptomycin. The aorta is then digested with elastase/collagenase in MEM. There is no disclosure of added antibiotics. The dissociated cells are then cultured in MEM with BSA, transferrin etc.. There is no disclosure of the addition of antibiotics.

The addition of the antibiotic in the first cell isolating step of the culturing process is a brief process, and the antibiotics which are penicillin and streptomycin (antibiotics which are used to treat animals including humans) are not present in the culturing steps. Applicants assert that the serum and recombinant growth factors make the product unsuitable for human consumption. First, the claim is not limited to human consumption. Second, this appears to be merely argument of counsel with no extrinsic evidence to support the assertion. Counsel's arguments cannot take the place of objective evidence. In fact, applicant's method on page 13, has a medium with 10% FCS in it. The examiner's position is the product of Yamamoto et al. is as edible as applicant's product.

Applicant argue that the product of Molnar et al. is not suitable for consumption because the use of fetal bovine serum renders this product unsuitable. Please look at the specification on page 13 where applicant uses fetal calf serum (FCS) in the growth medium.

Applicant further argues that the cells of Molnar et al. are not grown in a "real" 3D network. In the absence of concrete limitations in the claims, Molnar et al. teaches a 3D system that is as real as that claimed. That is, in three dimensional form. Please note that on page 13, applicant states that "Cells can be added to microcarriers such as Cytodex 1 and 3 beads". This is precisely what Molnar et al. teach.

Applicant argues that Molnar et al. does not grow the cells past 1 cell cycle. Please note that there are no limitations in the claims as to the number of divisions required and that applicant has not demonstrated even the achievement of 1 cell division in the specification, which is comprised of paper experiments.

Conclusion

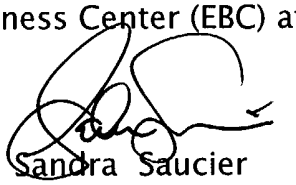
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651